

Amendments to the Claims

This listing of claims will replace all prior versions and listings of the claims in the application.

Listing of claims

1. (Presently Amended) A transdermal patch for administering a volatile liquid drug transdermally to a patient comprising
 - a) a top backing layer that is impermeable to the drug;
 - b) an intermediate, cast, amine-compatible solid silicone adhesive layer which underlies the backing layer, which has a thickness of from about 25 microns to about 100 microns, and contains from about 5 to about 50 wt.% of the drug based on the total dry weight of the drug and adhesive, and is a source in the patch of the drug;
 - c) a solid acrylic adhesive layer having a thickness of from about 25 microns to about 100 microns and comprising a copolymer prepared by copolymerizing (i) vinyl acetate, (ii) methacrylic acid, and (iii) at least one monomer selected from the group consisting of acrylate and methacrylate, and which underlies and is in diffusional contact with the silicone adhesive layer; and
 - d) a removable release liner layer underlying the acrylic adhesive layer,

wherein the relative thickness of layers "b" and "c", and the concentration of drug initially present in layer "b" is selected to provide a drug flux profile which is characterized by an initial period during which the flux rises to a level suitable for administering a therapeutic amount of the drug, and a second period during which the drug flux is sustained above said level, said second period lasting for at least twice as long as said initial period, and wherein the amount of drug in the patch is sufficient to provide a therapeutically effective amount of drug to the patient over a period of at least about several hours.

2. (Withdrawn) The transdermal patch of claim 1, wherein the drug is nicotine and the patch is capable of administering 0.2 to 1.5 mg. nicotine per hour to the patient.
3. (Previously Presented) The transdermal patch of claim 1, wherein the drug is a combination of nicotine and mecamylamine and the patch is capable of administering 0.2 to 1.5 mg nicotine per hour and 0.02 to 1 mg mecamylamine per hour to the patient.
4. (Withdrawn) The transdermal patch of claim 1 wherein the drug is selegiline and the patch is capable of administering 0.2 to 3 mg selegiline per day to the patient.
5. (Withdrawn) The patch of claim 1 wherein the drug is mecamylamine only and the patch is capable of administering 0.02 to 1 mg mecamylamine per hour to the patient.
6. (Previously Presented) The patch of claim 1 wherein the release liner layer is a siliconized release liner layer.
7. (Previously Presented) The patch of claim 1 wherein the acrylic adhesive layer is made from a blend of two acrylic adhesives.
8. (Withdrawn) A method of making a transdermal patch for administering a volatile liquid drug to a patient comprising:
 - (a) coating a solution of the drug and a silicone adhesive in hexane onto a backing layer;
 - (b) evaporating the hexane from the coating to form a layer of drug-containing silicone adhesive on the backing layer; and
 - (c) laminating an assembly comprising an acrylic adhesive coated onto a release liner layer onto the silicone adhesive layer on the backing layer such that the silicone adhesive layer and the acrylic adhesive layer are in diffusional contact with each other.
9. (Withdrawn) The method of claim 8 wherein step (b) is carried out at 30° to 40°.
10. (Withdrawn) The method of claim 8 wherein the release liner layer is a siliconized

release liner layer.

11. (Withdrawn) The method of claim 8 wherein the drug is nicotine.
12. (Withdrawn) The method of claim 8 wherein the drug is a combination of nicotine and mecamylamine.
13. (Withdrawn) The method of claim 8 wherein the drug is selegiline.
14. (Withdrawn) The method of claim 8 wherein the drug is mecamylamine only.
15. (Withdrawn) A method for treating a person for nicotine dependence comprising transdermally administering a therapeutically effective amount of mecamylamine without transdermal co-administration of nicotine to the person.
16. (Withdrawn) The method of claim 15 wherein the rate of mecamylamine administration is 0.02 to 1 mg/hr.
17. (Withdrawn) The method of claim 15 wherein the rate of mecamylamine administration is 0.1 to 0.6 mg/hr.
18. (Withdrawn) A method for treating a person for nicotine dependence comprising transdermally administering a therapeutically effective amount of mecamylamine to the person for a first time period during which the person smokes cigarettes as desired and continuing said administration for a second time period during which the person is advised to not smoke.
19. (Withdrawn) The method of claim 18 wherein the first time period is about 1 to about 4 weeks and the second time period is about 2 to about 12 weeks.
20. (Withdrawn) The method of claim 18 wherein the first time period is about 2 to about 3 weeks and the second time period is about 4 to 8 weeks.

21. (Withdrawn) A method for treating a woman for nicotine dependence comprising transdermally co-administering a therapeutically effective amount of nicotine and a therapeutically effective amount of mecamylamine to the woman.
22. (Withdrawn) The method of claim 21 wherein the rate of mecamylamine administration is 0.02 to 1 mg/hr and the rate of nicotine administration is 0.2 to 1.5 mg/hr.
23. (Withdrawn) The method of claim 21 wherein the rate of mecamylamine administration is 0.1 to 0.6 mg/hr and the rate of nicotine administration is 0.3 to 0.9 mg/hr.
24. (Withdrawn) A method for treating a woman for nicotine dependence comprising transdermally co-administering a therapeutically effective amount of nicotine and a therapeutically effective amount of mecamylamine to the woman for a first time period during which the woman smokes cigarettes as desired and continuing said administration for a second time period during which the woman is advised to not smoke.
25. (Withdrawn) The method of claim 24 wherein the first time period is about 1 to about 4 weeks and the second time period is about 2 to about 12 weeks.
26. (Withdrawn) The method of claim 24 wherein the first time period is about 2 to about 3 weeks and the second time period is about 4 to 8 weeks.
27. (Cancelled)
28. (Previously Presented) The patch of Claim 1, wherein the silicone adhesive layer comprises a silicone pressure sensitive adhesive.
29. (Cancelled)
30. (Previously Presented) The patch of Claim 28, wherein the acrylic adhesive layer comprises an acrylic pressure sensitive adhesive.

June 23, 2004

31. (Cancelled)

32. (Previously Presented) The patch of Claim 27, wherein the drug comprises a mixture of nicotine and mecamylamine.

33. (Previously Presented) The patch of Claim 28, wherein the drug comprises a mixture of nicotine and mecamylamine.

34. (Cancelled)

35. (Previously Presented) The patch of Claim 27, wherein said acrylic layer comprises about 2.5 wt. % to about 30 wt. % of the drug after equilibration.

36. (Previously Presented) The patch of Claim 3, wherein the patch contains an amount of drug sufficient to provide administration of the drug for a period of up to about 72 hours.

37. (Previously Presented) The patch of Claim 34, wherein the silicone layer contains 10 to 30 wt. % of the drug.

38. (Previously Presented) The patch of Claim 7, wherein the acrylic adhesives comprise a copolymer which is the polymerization product of a blend of monomers of which at least 50 wt. % are selected from the group consisting of 2-ethylhexyl acrylate, butylacrylate, and isooctyl acrylate.